

REMARKS

Claims 7-12 remain pending after this response.

Claim Amendments

By this amendment, claims 1-6 are canceled and rewritten as new claims 7-12. Support for claims 7-9 resides at least at page 1, lines 11-12, and page 4, lines 5-8. Support for claim 10 resides at page 4, lines 13-14 and previous claim 6. Support for claims 11-12 resides at least at page 4, lines 19-25. No new matter is added by this amendment.

Rejection under 35 USC 112 (paragraph two)

Claims 5 and 6 stand rejected under 35 USC 112 (paragraph two) as not distinctly claiming the invention. This rejection is respectfully traversed to the extent deemed to apply to the claims as amended.

In response, claims 5 and 6 are canceled. The rejection is thus moot and should be withdrawn.

Rejection of Claims 1 and 2 under 35 USC 102(b)

Claims 1 and 2 stand rejected under 35 USC 102(b) as being unpatentable over Yagi et al ‘138. This rejection is respectfully traversed to the extent deemed to apply to the claims as amended.

In response, claims 1 and 2 are canceled. This rejection is thus moot and should be withdrawn.

Rejection of Claims 3-6 under 35 USC 102(b)

Claims 3-6 stand rejected under 35 USC 102(b) over Yagi et al '754. This rejection is respectfully traversed to the extent deemed to apply to the claims as amended.

In response, claims 3-6 are canceled. The rejection is thus moot and should be withdrawn.

Rejection of Claims 1-6 under 35 USC 103(a)

Claims 1-6 stand rejected under 35 USC 103(a) as being unpatentable over Yagi et al '138 in view of Iwasaki et al. This rejection is respectfully traversed to the extent deemed to apply to the claims as amended.

In response, claims 1-6 are canceled. The rejection is thus moot and should be withdrawn.

Newly-Presented Claims

As noted above, claims 1-6 are canceled and replaced by new claims 7-12 directed to a method for treating an allergic disease of type I comprising externally administering an effective amount of 3'-hydroxymethyl-4-hydroxypyrrolido[1,2-f]2',5'-piperazinedione. The newly-presented claims patentably distinguish over the cited prior art for the following reasons.

The Examiner asserts that Yagi '138 teaches the compound (i.e. 3'-hydroxymethyl-4-hydroxypyrrolido[1,2-f]2',5'-piperazinedione) for treatment of liver damage, and Iwasaki and Kimata disclose the relation between liver problems and the allergies such as atopic dermatitis and rhinitis. The Examiner concludes that it is inherent that the compound would be effective in treating allergies including rhinitis and atopic dermatitis. The Examiner's position is without basis.

In response, the references (Iwasaki and Kimata) only disclose the relation between liver disease and allergy disease, and the references do not disclose that the liver disease causes the allergy disease. Further, these references do not teach that the atopic disease is improved by the treatment of liver disease. On the contrary, it is also possible that the liver disease is caused by the allergy disease.

Further, Iwasaki describes that there is some relationship between atopic dermatitis and liver dysfunction, since the serum GOT levels of atopic dermatitis patients are higher than normal. On the other hand, Kimata describes "the severity of fatty liver was not associated with liver dysfunction in that the serum levels of GOT and GPT were within normal limits in most of the patients with fatty liver" (the last paragraph of middle column). The contents of Iwasaki and Kimata are thus contradictory.

Moreover, according to Kimata, only 17.6% of the atopic dermatitis patient has fatty liver (see Table 1 of Kimata). Therefore, fatty liver is not thought to be a main factor in the cause of atopic dermatitis.

According to the Examiner's view, all medicines used for the treatment of liver diseases will be effective in the treatment of an allergy disease.

However, Iwasaki and Kimata merely disclose the relation between liver problems and allergies, and these references do not teach that liver disease causes the allergy disease. Further, these references do not show that the atopic disease is improved by the treatment of liver disease. Also, it is illogical for the person skilled in the art to conclude that medicines used for the treatment of liver diseases can be effective in the treatment of an allergy disease. Therefore, applicants believe it is not inherent that the compound is effective in treating allergies as asserted by the Examiner.

In view of the above claim amendments and arguments, the newly-presented claims are believed to be directed to allowable subject matter.

The application is in condition for allowance, and an early indication of same earnestly is solicited.

Payment in the amount of \$1050.00 is submitted herewith as payment for the requested three month extension of time.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

By *Gerald M. Murphy Jr.* #28,808 f
Gerald M. Murphy, Jr.
Registration No.: 28,977
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road, Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant